

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Jaime A. Rabi	Patent No.: 7,582,748 B2
Application No.: 10/806,296	Issue Date: September 1, 2009
Filed: March 22, 2004	Attorney Docket No.: 11874-010-999
For: METHODS OF MANUFACTURE OF 2'- DEOXY- β -L-NUCLEOSIDES	

**REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

MAIL STOP PATENT EXT.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

United States Patent No. 7,582,748 B2 issued on September 1, 2009 and indicates a patent term adjustment under 35 U.S.C. § 154(b) of 0 days.

Applicants hereby respectfully request reconsideration of the patent term adjustment indicated in the above-identified patent. Specifically, Applicants believe that the patent term adjustment should be increased by 230 days to a total of 230 days.

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(d) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;

- (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
- (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
- (B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

In support of this request, Applicants submit the following:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be **\$200.00**.

Please charge the required fee to Jones Day Deposit Account No. 50-3013 (referencing 417451-999010).

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702(b)(2), Applicants submit the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is 230 days, which is attributable to (a) the failure of the United States Patent and Trademark Office (“USPTO”) to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the above-referenced U.S. Patent Application No. 10/806,296 (“the ’296 application”) was filed under 35 U.S.C. § 111(a) (delay under 37 C.F.R. § 1.702(a)(1)); and (b) the failure of the USPTO to

issue a patent within three years of the actual filing date of the '296 application (delay under 37 C.F.R. § 1.702(b)).

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

(a) Delay under 37 C.F.R. § 1.702(a)(1)

The delay by the USPTO under 37 C.F.R. § 1.702(a)(1) is 270 days.

As acknowledged by the USPTO in its calculation of the patent term adjustment, the USPTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date of filing of the '296 application. *See* USPTO's Patent Application Information Retrieval page for U.S. Patent Application No. 10/806,296, at Patent Term Adjustment History ("USPTO PAIR Adjustment," Exhibit A). The '296 application was filed under 35 U.S.C. § 111(a) on March 22, 2004. The first notification under 35 U.S.C. § 132 (a Restriction Requirement) was mailed by the USPTO on February 16, 2006. Accordingly, the USPTO did not mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 within fourteen months after the date on which the application was filed (or by May 22, 2005), and thus, the term of the patent should have been adjusted because the notification under 35 U.S.C. § 132 was delayed by 270 days, which is the period of time from May 22, 2005 to February 16, 2006. 37 C.F.R. § 1.702(a)(1).

(b) Delay under 37 C.F.R. § 1.702(b)

The delay by the USPTO under 37 C.F.R. § 1.702(b) is 249 days.

According to 35 U.S.C. § 154(b)(1)(B): "GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY - Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including- (i) any time consumed by continued examination of the

application requested by the applicant under section 132(b)”
See 35 U.S.C. § 154(b)(1)(B).

Further, Applicants note that pursuant to 35 U.S.C. § 154(b)(1)(B)(i), referenced above, “[t]he filing of a RCE cuts-off the applicant’s ability to accumulate any additional patent term adjustment against the three-year pendency provision, but does not otherwise affect patent term adjustment.” *See* www.uspto.gov/web/offices/dcom/olia/aipa/comparison_of_cpa_practice.htm; “Comparison of CPA practice, URAA transitional practice under 37 CFR 1.129(a), and new request for continued examination (RCE) practice.”

The ’296 application was filed under 35 U.S.C. § 111(a) on March 22, 2004. A Request for Continued Examination (“RCE”) under 35 U.S.C. § 132(b) was filed on November 26, 2007.

Accordingly, the USPTO failed to issue a patent within three years of the date on which the application was filed (or by March 22, 2007), and thus, the term of the patent should have been adjusted because issuance was delayed by 249 days, which is the period of time from March 22, 2007 to the filing date of the RCE, November 26, 2007. 37 C.F.R. § 1.702(b). This delay in issuance of the patent was not included by the USPTO in its calculation of patent term adjustment (*see* “USPTO PAIR Adjustment,” Exhibit A).

According to 35 U.S.C. § 154(b)(2)(A): “To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed ...” (emphasis added). *See* 35 U.S.C. § 154(b)(2)(A).

According to 37 C.F.R. § 1.703(f): “The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not *overlapping* ...” (emphasis added). *See* 37 C.F.R. § 1.703(f).

Applicants respectfully submit that under controlling case law the delay under 37 C.F.R. § 1.702(a)(1) does not overlap the delay under 37 C.F.R. § 1.702(b) for the '296 application.

In *Wyeth et al. v. Dudas* (hereinafter *Wyeth*) the District Court for the District of Columbia clarified the meaning of 35 U.S.C. § 154(b)(2)(A). See *Wyeth et al. v. Dudas*, Civil Action No. 07-1492 (JR), United States District Court for the District of Columbia, 2008 U.S. Dist. LEXIS 76063 (D.D.C., September 30, 2008), attached hereto as Exhibit B. In *Wyeth*, the court held that: "The only way that periods of time can 'overlap' is if they occur on the same day. If an 'A delay' occurs on one calendar day and a 'B delay' occurs on another, they do not overlap." *Wyeth*, 2008 U.S. Dist. LEXIS 76063, 9-10.

Turning to the '296 application, the period of delay under 37 C.F.R. § 1.702(a)(1) occurred from May 22, 2005, fourteen months from the date on which the application was filed, to February 16, 2006, the date on which a Restriction Requirement was mailed by the USPTO. The period of delay under 37 C.F.R. § 1.702(b) occurred from March 22, 2007, three years from the date on which the application was filed, to November 26, 2007, the date the RCE was filed. Thus, the delay under 37 C.F.R. § 1.702(a)(1) (May 22, 2005 to February 16, 2006) occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b) (March 22, 2007 to November 26, 2007). Consequently, under 35 U.S.C. § 154(b)(2)(A), the delay under 37 C.F.R. § 1.702(a)(1) does not overlap the delay under 37 C.F.R. § 1.702(b) for the '296 application, and therefore the total delay under 37 C.F.R. § 1.702 for the adjustment should be a summation of the delays under 37 C.F.R. § 1.702(a)(1) and 37 C.F.R. § 1.702(b), or 519 days (the sum of 270 and 249 days).

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.”

The patent term adjustment calculated by the USPTO correctly included the time period under 37 C.F.R. § 1.702(a)(1) for the period beginning May 22, 2005 (fourteen months after the date on which the ’296 application was filed) and ending February 16, 2006, the date the Restriction Requirement was mailed from the USPTO. Applicants confirm that this period consists of 270 days.

An adjustment is sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)...and ending on the date a patent was issued.”

Applicants submit that this period consists of 249 days, which is the period of time three years from the filing date of the ’296 application, March 22, 2007 to the filing date of the RCE, November 26, 2007. Applicants further submit that the delay under 37 C.F.R. § 1.702(a)(1) does not overlap the delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Applicants believe that the delays attributable to the USPTO under 37 C.F.R. § 1.702 total 519 days (the sum of 270 and 249 days), not 270 days as calculated by the USPTO.

2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in section (i) above, Applicants believe that the total delay by the USPTO under 37 C.F.R. § 1.702(a)(1) and (b) amounts to 519 days. As discussed in section (iv) below, Applicants believe that the total delay attributable to Applicants under 37 C.F.R. § 1.704 amounts to 289 days. Applicants believe that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 330 days, which is the sum of the periods calculated under 37 C.F.R. §§ 1.703(a) through (e) (*i.e.*, 519 days), to the extent that such periods are not overlapping, less the sum of the periods calculated under 37 C.F.R. § 1.704 (*i.e.*, 230 days).

- (iii) The '296 application is not subject to a terminal disclaimer.
- (iv) The circumstances during the prosecution of the '296 application that might constitute a failure to engage in reasonable efforts to conclude processing or examination of the '296 application as set forth in 37 C.F.R. § 1.704 are believed to consist of 289 days (*see* "USPTO PAIR Adjustment," Exhibit A), and are as follows:

- 1. a delay of 66 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of a Response on July 21, 2006 to the Restriction Requirement mailed on February 16, 2006;
- 2. a delay of 86 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of a Response on April 12, 2007 to the non-final Rejection mailed on October 16, 2006;
- 3. a delay of 61 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of a Response on May 28, 2008 to the non-final Rejection mailed on December 28, 2007; and
- 4. a delay of 76 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of an Amendment and a Notice of Appeal on February 16, 2009 in response to Final Rejection mailed on September 2, 2008.

37 C.F.R. § 1.704(b) provides, in relevant part: “[A]n applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed.”

The patent term adjustment calculated by the PTO correctly included the above time periods under 37 C.F.R. § 1.704(b). *See* PTO PAIR Adjustment, Exhibit A. Applicants confirm that the sum of the above time period consists of 289 days.

CONCLUSION

In summary, the total adjustment under 37 C.F.R. § 1.702(a)(1) and (b) is 519 days, the total delays attributable to Applicants under 37 C.F.R. § 1.704 are 289 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 230 days. Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 230 days.

Applicants submit that the issues raised in this request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(d), which provides in relevant part, that “[a]ny request for reconsideration under this section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues.”

Applicants submit that the issues raised in this request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(d), as knowledge of the actual date the patent issues is required to calculate any additional patent term patentee is entitled to for the PTO’s failure to issue the patent within three years.

In accordance with 37 C.F.R. § 1.705(d), this request for reconsideration of patent term adjustment is filed within two months of September 1, 2009, the issue date of the 7,582,748 B1 patent (Monday, November 2, 2009 is the first patent office business day following the Sunday, November 1, 2009 deadline). Thus, this request for reconsideration of patent term adjustment is timely filed.

Respectfully submitted,

Date: November 2, 2009



Rahul Pathak

42,983

(Reg. No.)

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EXHIBIT A: USPTO PAIR Adjustment

10/806,296	METHODS OF MANUFACTURE OF 2'-DEOXY-BETA-L-NUCLEOSIDES	11-02-2009::17:51:37
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/806,296

Filing or 371(c) Date:	03-22-2004	USPTO Delay (PTO) Delay (days):	270
Issue Date of Patent:	09-01-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	289
Post-Issue Petitions (days):	+0	Total PTA (days):	0
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
08-12-2009	PTA 36 Months		
09-01-2009	Patent Issue Date Used in PTA Calculation		
07-21-2009	Dispatch to FDC		
07-20-2009	Application Is Considered Ready for Issue		
07-16-2009	Issue Fee Payment Verified		
07-16-2009	Issue Fee Payment Received		
04-17-2009	Mail Notice of Allowance		
04-07-2009	Document Verification		
04-03-2009	Notice of Allowance Data Verification Completed		
03-16-2009	Mail Examiner Interview Summary (PTOL - 413)		
02-12-2009	Examiner Interview Summary Record (PTOL - 413)		
02-16-2009	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received		
03-03-2009	Date Forwarded to Examiner		
02-16-2009	Amendment/Argument after Notice of Appeal		
02-16-2009	Notice of Appeal Filed		76
02-16-2009	Request for Extension of Time - Granted		↑
02-12-2009	Examiner Interview Summary Record (PTOL - 413)		↑
09-02-2008	Mail Final Rejection (PTOL - 326)		↑
08-29-2008	Final Rejection		
06-21-2008	Date Forwarded to Examiner		
05-28-2008	Response after Non-Final Action		61
05-28-2008	Request for Extension of Time - Granted		↑
06-05-2008	Change in Power of Attorney (May Include Associate POA)		↑
06-02-2008	Correspondence Address Change		↑
12-28-2007	Mail Non-Final Rejection		↑
12-26-2007	Non-Final Rejection		
12-07-2007	Date Forwarded to Examiner		
12-07-2007	Date Forwarded to Examiner		
11-26-2007	Request for Continued Examination (RCE)		
12-07-2007	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		

11-26-2007	Request for Extension of Time - Granted	
11-26-2007	Workflow - Request for RCE - Begin	
10-03-2007	Mail Advisory Action (PTOL - 303)	
10-01-2007	Advisory Action (PTOL-303)	
09-21-2007	Date Forwarded to Examiner	
09-07-2007	Amendment/Argument after Notice of Appeal	
09-07-2007	Notice of Appeal Filed	
07-30-2007	Miscellaneous Incoming Letter	
06-25-2007	Mail Final Rejection (PTOL - 326)	
06-21-2007	Final Rejection	
04-13-2007	Date Forwarded to Examiner	
04-12-2007	Response after Non-Final Action	86
04-12-2007	Request for Extension of Time - Granted	⬆
04-12-2007	New or Additional Drawing Filed	⬆
10-16-2006	Mail Non-Final Rejection	⬆
10-02-2006	Non-Final Rejection	
09-13-2004	Information Disclosure Statement considered	
07-21-2006	Information Disclosure Statement considered	
07-21-2006	Reference capture on IDS	
07-21-2006	Information Disclosure Statement (IDS) Filed	
07-21-2006	Information Disclosure Statement (IDS) Filed	
07-31-2006	Date Forwarded to Examiner	
07-21-2006	Response to Election / Restriction Filed	66
07-21-2006	Request for Extension of Time - Granted	⬆
07-21-2006	Request for Extension of Time - Granted	⬆
02-16-2006	Mail Restriction Requirement	270
02-15-2006	Requirement for Restriction / Election	⬆
12-21-2005	IFW TSS Processing by Tech Center Complete	⬆
12-21-2005	Case Docketed to Examiner in GAU	⬆
09-13-2004	Reference capture on IDS	⬆
09-13-2004	Information Disclosure Statement (IDS) Filed	⬆
09-13-2004	Information Disclosure Statement (IDS) Filed	⬆
09-23-2004	Application Return from OIPE	⬆
09-23-2004	Application Is Now Complete	⬆
09-23-2004	Application Return TO OIPE	⬆
09-23-2004	Application Return from OIPE	⬆
09-23-2004	Application Return TO OIPE	⬆
09-23-2004	Application Dispatched from OIPE	⬆
09-23-2004	Application Is Now Complete	⬆
09-07-2004	Additional Application Filing Fees	⬆
09-07-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	⬆

06-07-2004	Notice Mailed--Application Incomplete--Filing Date Assigned	⌵
04-16-2004	Cleared by OIPE CSR	⌵
03-30-2004	IFW Scan & PACR Auto Security Review	⌵
03-22-2004	Initial Exam Team nn	⌵

Close Window

EXHIBIT B:

***Wyeth et al. v. Dudas*, Civil Action No. 07-1492 (JR), United States District Court for the
District of Columbia, 2008 U.S. Dist. LEXIS 76063 (D.D.C., September 30, 2008)**

1 of 1 DOCUMENT

**WYETH, et al., Plaintiffs, v. JON W. DUDAS, Under Secretary of Commerce for
Intellectual Property and Director of U.S. Patent and Trademark Office, Defendant.**

Civil Action No. 07-1492 (JR)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2008 U.S. Dist. LEXIS 76063

September 30, 2008, Filed

COUNSEL: [*1] WYETH, Plaintiff: David O. Bickart, LEAD ATTORNEY, Patricia A. Carson, PRO HAC VICE, KAYE SCHOLER LLP, Washington, DC.

For ELAN PHARMA INTERNATIONAL LIMITED, Plaintiff: David O. Bickart, LEAD ATTORNEY, KAYE SCHOLER LLP, Washington, DC.

For JON W. DUDAS, Honorable, Under Secretary of Commerce, Defendant: Fred Elmore Haynes, LEAD ATTORNEY, U.S. ATTORNEY'S OFFICE, Washington, DC.

JUDGES: JAMES ROBERTSON, United States District Judge.

OPINION BY: JAMES ROBERTSON

OPINION

MEMORANDUM OPINION

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. *Section 154(a)(2)* establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution [*2] takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap,

Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. *See 35 U.S.C. § 154 (1992)* ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. *See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994)*. [*3] In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. *Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999)*.

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in *subsection (b)(1)(A)*, the "[g]uarantee of prompt Patent and Trademark Office response." It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated

statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. *See* 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called "A delays" or "A periods." The second provision is the "[g]uarantee of no more than 3-year application pendency." Under this provision, a one-day [*4] term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO. ¹ *See* 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period." ("C delays," delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

I Certain reasons for exceeding the three-year pendency period are excluded, *see* 35 U.S.C. § 154(b)(1)(B)(i)-(iii), as are periods attributable to the applicant's own delay. *See* 35 U.S.C. § 154(b)(2)(C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer [*5] the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, *see* 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under [*6] 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is 1/1/07, but the patent does not [*7] issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under *Chevron v. NRDC*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). No,

the plaintiffs argue, because, under the Supreme Court's holdings in *Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006), and *United States v. Mead Corp.*, 533 U.S. 218, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001), Congress has not "delegated [*8] authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority. See *Gonzales*, 546 U.S. at 255-56, citing *Mead*, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded *Chevron* deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in *Merck*, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant [*9] to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). *Chevron* deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at *Chevron's* "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., *MCI v. AT&T*, 512 U.S. 218, 229, 114 S. Ct. 2223, 129 L. Ed. 2d 182 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not [*10] overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its inter-

pretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" *always overlaps* with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if [*11] plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefited by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and *no more*, it could easily have been written that way. It is true that the legislative context -- as distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to [*12] prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON

United States District Judge